

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION
(PCT Rule 61.2)

To:

Assistant Commissioner for Patents
United States Patent and Trademark
Office
Box PCT
Washington, D.C.20231
ETATS-UNIS D'AMERIQUE

Date of mailing:

03 August 2000 (03.08.00)

in its capacity as elected Office

International application No.:

PCT/SE00/00017

Applicant's or agent's file reference:

Pha-1812/PCT

International filing date:

12 January 2000 (12.01.00)

Priority date:

26 January 1999 (26.01.99)

Applicant:

LEVANDER, Gustav et al

1. The designated Office is hereby notified of its election made:

in the demand filed with the International preliminary Examining Authority on:

31 May 2000 (31.05.00)

in a notice effecting later election filed with the International Bureau on:

2. The election was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer:

J. Zahra

Telephone No.: (41-22) 338.83.38

THIS PAGE BLANK (USPTO)

PATENT COOPERATION TREA

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference Pha-1812/PCT	FOR FURTHER ACTION		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/SE00/00017	International filing date (day/month/year) 12.01.2000	Priority date (day/month/year) 26.01.1999	
International Patent Classification (IPC) or national classification and IPC ₇ B 32 B 27/06, B 65 D 75/26, C 08 G 63/189, C 08 G 63/60			
Applicant Pharmacia & Upjohn AB et al			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I Basis of the report
- II Priority
- III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV Lack of unity of invention
- V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI Certain documents cited
- VII Certain defects in the international application
- VIII Certain observations on the international application

Date of submission of the demand 31.05.2000	Date of completion of this report 07.05.2001	
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. 08-667 72 88	Telex 17978 PATOREG-S	Authorized officer Helena Danielsson/Els Telephone No. 08-782 25 00

THIS PAGE BLANK (USPTO)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE00/00017

I. Basis of the report

1. With regard to the elements of the international application:*

 the international application as originally filed the description:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

 the claims:

pages _____, as originally filed

pages _____, as amended (together with any statement) under article 19

pages _____, filed with the demand

pages _____, filed with the letter of _____

 the drawings:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

 the sequence listing part of the description:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

 the language of a translation furnished for the purposes of international search (under Rule 23.1(b)). the language of publication of the international application (under Rule 48.3(b)). the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

 contained in the international application in written form. filed together with the international application in computer readable form. furnished subsequently to this Authority in written form. furnished subsequently to this Authority in computer readable form. The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished. The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.4. The amendments have resulted in the cancellation of: the description, pages _____ the claims, Nos. _____ the drawings, sheet/fig _____5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2 (c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.

THIS PAGE BLANK (USPTO)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE00/00017

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- restricted the claims.
- paid additional fees.
- paid additional fees under protest.
- neither restricted nor paid additional fees.

2. This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with rules 13.1, 13.2 and 13.3 is

- complied with.
- not complied with for the following reasons:

I. Claim 1, 3-4 and parts of 6-13 relates to a material for packaging a nicotine-containing product, which material comprises a polymer based on dimethyl-2,6-naphthalene dicarboxynate and/or 2,6-naphthalene dicarboxylic acid monomers.

II. Claim 2, 4 and parts of 6-13 relate to a material for packaging a nicotine-containing product, which material comprises a liquid crystal polymer, LCP.,

The special technical feature of invention I is a polymer based on dimethyl-2,6-naphthalene dicarboxynate and/or 2,6-naphthalene dicarboxylic acid monomers.

The special technical feature of invention II is a polymer based on a liquid crystal polymer.

The special technical feature of invention II is not the same as or corresponding to the special technical feature of invention I.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- all parts.
- the parts relating to claims Nos. _____

THIS PAGE BLANK (USPTO)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE00/00017

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>1-13</u>	YES
	Claims	_____	NO
Inventive step (IS)	Claims	<u>1-13</u>	YES
	Claims	_____	NO
Industrial applicability (IA)	Claims	<u>1-13</u>	YES
	Claims	_____	NO

2. Citations and explanations (Rule 70.7)

The claimed invention relates to materials for packaging nicotine-containing products.

The problem to be solved by the invention is to provide a material that exhibits favourable characteristics of oxygen, water and nicotine impermeability and that is favourable to process.

This is accomplished by materials comprising a polymer based on dimethyl-2,6-naphthalene dicarboxynate, 2,6-naphthalene dicarboxylic acid monomers and/or a liquid crystal polymer.

The relevant documents cited in the International Search Report were:

D1 WO 9109731
 D2 EP 0656389
 D3 US 5326848

Document D1 discloses a material for producing a nicotine maintenance product. The nicotine barrier material contains 75% acrylonitrile and 25% methyl acrylate. The claimed invention differs from D1 in that the material disclosed in D1 does not comprise dimethyl-2,6-naphthalene dicarboxynate, 2,6-naphthalene dicarboxylic acid monomers or a liquid crystal polymer.

.../...

THIS PAGE BLANK (USPTO)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE00/00017

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: V

In D2 an easy-open film comprising a resin composed mainly of polyethylene-2,6-naphthalene is disclosed. The difference between the claimed invention and D2 is that D2 does not mention the use of polyethylene-2,6-naphthalene in a material as a nicotine barrier or for packaging a nicotine-containing product.

Document D3 makes known a packaging material comprising a liquid crystal polymer. However, this document does not mention the use of this liquid crystal polymer in materials for packaging nicotine-containing products and consequently, the claimed invention differs from D3.

In view of the above, it is not considered obvious to a person skilled in the art to use dimethyl-2,6-naphthalene dicarboxynate, 2,6-naphthalene dicarboxylic acid monomers and/or a liquid crystal polymer for making a material used for packaging nicotine-containing products.

Accordingly, the claimed invention in claims 1-13 is considered to fulfil the requirements of novelty, technical applicability and inventive step.

THIS PAGE BLANK (USPTO)

PCTWORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : B32B 27/06, B65D 75/26, C08G 63/189, 63/60		A1	(11) International Publication Number: WO 00/44559 (43) International Publication Date: 3 August 2000 (03.08.00)
(21) International Application Number: PCT/SE00/00017 (22) International Filing Date: 12 January 2000 (12.01.00)		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).	
(30) Priority Data: 9900215-6 26 January 1999 (26.01.99) SE		Published <i>With international search report.</i>	
(71) Applicant (<i>for all designated States except US</i>): PHARMACIA & UPJOHN AB [SE/SE]; S-112 87 Stockholm (SE).			
(72) Inventors; and			
(75) Inventors/Applicants (<i>for US only</i>): LEVANDER, Gustav [SE/SE]; Tullingebergsvägen 32, S-146 45 Tullinge (SE). KARLSSON, Anders, H., F. [SE/SE]; Per Wickenbergs-gatan 1, S-217 54 Malmö (SE). HILDINGSSON, Ingemar [SE/SE]; Smedjegatan 2 C, S-222 37 Lund (SE).			
(74) Agent: HEDENSTRÖM, John; Pharmacia & Upjohn AB, Box 941, S-251 09 Helsingborg (SE).			

(54) Title: NEW USE

(57) Abstract

A material for packaging a nicotine containing product comprising a polymer based on dimethyl-2,6-naphthalene dicarboxynate or 2,6-naphthalene dicarboxylic acid monomers, such as polyethylene naphtalate (PEN) or polytrimethylene naphtalate (PTN), or a liquid crystal polymer (LCP). The material may be laminated to another polymer or to metal foil.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

NEW USE**Technical field**

The present invention relates to materials for packaging nicotine-containing products.

Background art

For many years tobacco smoking has been one of the major health problems throughout the world. Smoking is now recognized as the main cause for e.g. high blood pressure and lung cancer. However, because of the addictive nature of nicotine it is utterly difficult for heavy smokers to completely stop smoking. An acceptable alternative to smoking has been to provide nicotine in a form or manner other than by smoking, e.g. as a chewing gum containing nicotine as an active ingredient, see e.g. US 3,845,217. Other products used as substitutes for smoking are tablets containing nicotine, see e.g. US 5,543,424, devices for allowing nicotine to be inhaled through an elongated tube, see e.g. US 5,501,236, nicotine containing nasal sprays, see e.g. US 5,656,255, patches for administering nicotine transdermally, see e.g. US 4,915,950, etc.

The primary requirement when packaging drugs and food is the demand that the package must protect the product against penetration of moisture and oxygen from the environment. Very seldom the product itself constitutes any problems. Nicotine, on the other hand, is very aggressive towards its environment and migrates through most known materials. It is also very hygroscopic and therefore sensitive to moisture and when exposed to oxygen or air the nicotine turns brown. Because of the toxicity of nicotine and because the expected shelf-life for nicotine containing products is as long as up to two years, commonly used materials within the package industry, e.g. polypropylene, polyethylene and polyvinyl chloride therefore cannot be used for nicotine containing products.

A known polymer which fulfills the requirements of oxygen, water and nicotine impermeability is commercially available under the trademark Barex®, being a copolymer made of acrylonitrile and methylmethacrylate and grafted to nitrile rubber on the main chain. Due to the copolymerization with methylmethacrylate the polymer becomes softer and is possible to process. Barex® is available with different amounts of nitrile rubber, is amorphous and is a glass polymer at room temperature.

The temperature range within which Barex® may be processed is, however, very narrow rendering the polymer difficult to process resulting in a large amount of discarded material. This is partly due to Barex® having a temperature dependent elasticity. Today, Barex® is also associated with a high price.

5 The use of Barex® in a nicotine impermeable container is disclosed in US 5,501,236.

Summary of the invention

It is therefore an object of the present invention to provide an alternative material to Barex®, which exhibits favorable characteristics of oxygen, water and nicotine impermeability, but which does not suffer from the above-mentioned drawbacks. According to 10 the invention it is therefore suggested an alternative nicotine impermeable packaging material for a nicotine-containing product having the characterizing features of the claims.

15 The material of the invention comprises polyethylene naphtalate, polytrimethylene naphtalate and/or a liquid crystal polymer, LCP, and has excellent characteristics of oxygen, water and nicotine impermeability. Due to the temperature ranges the polymers of the invention are favorable to process and will have an acceptable price. The material of the invention is known *per se*, but its excellent nicotine barrier properties have not been known. Neither has its use for making packages for nicotine-containing products been 20 contemplated.

Detailed description of the invention

25 The packaging material of the invention is intended for use in connection with nicotine containing products for therapeutic treatment of patients having an addiction to nicotine. Examples of such products are chewing gums, sublingual tablets, nasal sprays, nicotine patches and nicotine inhaling devices, all marketed through Pharmacia & Upjohn. These products are all classified as drugs and thus, the requirements of product stability are high. The expected shelf life is two years without any noticeable change regarding composition, concentration and dosage. Specific ranges for allowed variations 30 have been established in accordance with requirements from the authorities, e.g. Food and Drug Administration, FDA, in the USA.

In chewing gums the nicotine is usually present in the form of a complex with an insoluble cation-exchanger, which is disbursed in a gum base, in order to be stabilized. In

tablets the nicotine is usually present in the form of an inclusion complex. Only small amounts, if any, of nicotine are in contact with the package for chewing gums and tablets and thus, the demand for a nicotine barrier becomes lower for these products. The pH for a chewing gum is usually slightly above 4.

5 In nasal spray the nicotine is present in a liquid solution having a concentration of approximately 10 mg/ml and a pH of approximately 7. The nasal spray is distributed in glass flasks inert to the aggressiveness of nicotine. However, the nicotine solution also comes into contact with seals and pumping devices made of polymeric material.

10 In a patch and in an inhaling device primarily nicotine vapor comes into contact with the package. Here the concentration depends on the vapor pressure of the nicotine that varies with temperature. In room temperature the concentration in a patch is approximately 250 mg/ml. In a patch and in an inhaling device the pH is approximately 9 - 10.

15 A number of factors are important when materials for nicotine-containing packages are chosen. The nicotine must not migrate through the packaging material and disappear from the system or be accumulated uncontrollably in the packaging material. Also, the nicotine must be protected from oxygen due to the fact that it is easily decomposed in contact with air or oxygen. Products containing nicotine also turns brown or yellow when only small amounts of decomposition products are present resulting in cosmetic 20 drawbacks long before any stability limits have been passed. A good oxygen barrier is therefore of utmost importance.

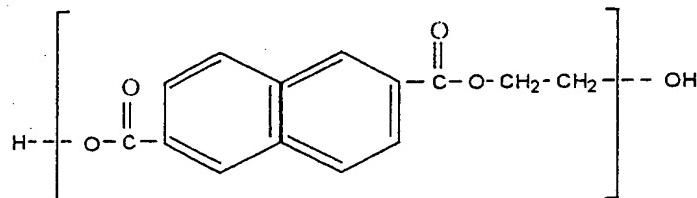
25 Besides the above mentioned primary demands on good nicotine resistance and low oxygen permeability, other important factors to take into consideration regarding packaging materials for nicotine-containing products are water and moisture permeation, processability, price and environmental impact.

The water barrier is important especially in the nasal spray where loss of water has large impact on the concentration of the product. Water barrier characteristics are also important in other forms of distribution since water may have an impact on permeation characteristics of the polymer. Great consideration should also be taken to the processability since large-scale industrial production is considered where even small problems 30 may involve large costs.

With the aim to find a packaging material for the packaging of a nicotine-containing product, which fulfills the above mentioned demands two different types of polymers, were found.

The first of these materials is PEN, polyethylene naphtalate:

5



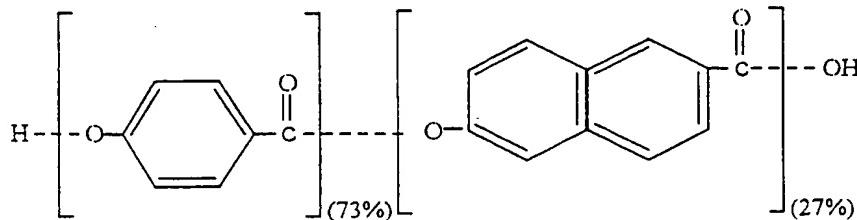
PEN is polyester based on dimethyl-2,6-naphthalene dicarboxynate or 2,6-naphthalene dicarboxylic acid monomers. Dimethyl-2,6-naphthalene dicarboxynate and -2,6-naphthalene dicarboxylic acid monomers are e.g. sold by Amoco under the trade name NDC and NDA-monomer respectively. PEN is semicrystalline and is a glass polymer at room temperature.

There are other polymers, such as PTN (polytrimethylene napthalate) which are based on the same monomers. PTN differs from PEN only in that the ethylene chain has been exchanged to a propylene chain. It is also envisageable to use polymers comprising both dimethyl-2,6-naphthalene dicarboxynate or 2,6-naphthalene dicarboxylic acid monomers.

PEN differs from PET (polyethylene tereftalate), which is another, more commonly used polyester, in that the benzene ring in the PET molecule has been exchanged for naphtene in PEN. This makes the PEN structure more rigid than the PET structure and the features of PEN more favorable for this invention than the features of PET.

The second nicotine impermeable polymer of the invention is polyester based Liquid Crystal Polymer, LCP. One example thereof is Vectra[®] A 530 having the following structure:

25



LCPs constitute a group of materials, which have a characteristic molecular structure. LCP polymers consist of rigid rod-like macromolecules that align in the melt to produce a liquid-like structure. This specific structure brings considerable improvement
 5 in mechanical properties compared with conventional polymers and a number of other exceptional properties. The monomers are hydroxy benzoic acid and hydroxy naphtenic acid. A typical LCP polymer, such as the above-mentioned Vectra[®] A 530, is filled with 30 % of mineral filler. The LCP material has a dense structure as a consequence of high crystallinity, is chemically resistant and has extremely low diffusion rates for oxygen and
 10 water.

According to the invention it was surprisingly found that in addition to the above mentioned barrier properties against water and oxygen PEN, PTN and LCP also exhibit excellent barrier properties against nicotine. In below Table 1 is shown a comparison of the properties of Barex[®] 210, PEN 14991 and Vectra[®] A 530. For comparison is added a
 15 polymer, Isoplast 2530 (a polyurethane having better barrier characteristics than other polyurethanes due to its high glass transition temperature), which does not have good nicotine impermeability.

Barex[®] is marketed by British Petroleum, PEN by Shell and by Eastman, Vectra[®] by Ticona and Isoplast by Dow.

20

Table 1

Material Properties				
Material	Barex 210	PEN 14991	Vectra A 530	Isoplast 2530
Opacity	Transparent	Transparent	Opaque	Transparent
Morphology				
Crystallinity	Amorphous	Semi crystalline	High Crystalline	Amorphous
Permeability				
Oxygen cm ³ ·mm/m ² ·day·atm	0,3	1,5	0,02	2,4
Water, g·mm/m ² ·day	2,0	0,7	0,05	1,2

Material Properties				
Material	Barex 210	PEN 14991	Vectra A 530	Isoplast 2530
Nicotine Resistance	Excellent	Excellent Equivalent to Barex	Excellent Equivalent to Barex	Not acceptable Inferior to Barex
Processing				
Extrusion	+	+	+	+
Injection Molding	+	+	+	+
Vacuum	+	+	-	
Forming				
Blow Molding	+	+		+
Applications				
Film	+	+	+	+
Laminate	+	+	+	+
Injection Mould details	+	+	+	+
Blow Mould details	+	+		+
Blisters	+	+	-	

The nicotine resistance of the captioned polymer materials was investigated with sorption tests as follows. Pieces of the respective materials were placed in glass bottles containing nicotine solution and were stored therein at room temperature for 1, 2 and 5 weeks. Subsequently the amounts of nicotine sorbed into the respective polymer materials were extracted from the polymers and analyzed by UV, HPLC and GC. The values for Barex 210 were used as reference levels.

As explained above PTN, marketed through Shell, is chemically very similar to PEN. In polymer chemistry it is a commonly accepted principle that close chemical similarity implies similar physical/chemical properties. Hence the above good results for PEN 10 implies that also PTN has good nicotine barrier properties.

The nicotine impermeable polymers PEN and PTN of the invention can be used alone in film applications or may be combined with other barrier materials in a laminate to further improve the barrier characteristics of the packaging material. Suitable materials 15 for laminating are metal, especially aluminium, foils and other polymers, e.g. polyacrylonitrile (PAN), polyamide (PA), polyvinylidene chloride (PVDC), and fluoropolymers, all of which are good oxygen and water barriers. Other polymer materials also suitable are

ethylene vinyl alcohol copolymer (EVOH) and polyvinyl alcohol (PVA), which are excellent oxygen barriers, and ionomers (i.e ionically crosslinked thermoplastic polymers, whereof Surlyn® from DuPont is an example), polyethylene (PE), and polypropylene (PP), which have good water barrier properties.

5 LCP is most suitable for use in injection molded applications. PEN, PTN and LCP may be alloyed with other polymers, such as PET. Such an alloy can then be processed as PET, but due to the incorporation of PEN, PTN or an LCP the alloy is conferred superior barrier properties compared to pure PET.

10 The invention will now be further described and illustrated by reference to the following example. It should be noted that this example should not be construed as limiting the invention in any way.

Example 1

15 An endless sheet of aluminium foil, which optionally on one face is laminated with a thin polymer layer, of e.g. polyethylene or polyethylene terephthalate, is rolled off from a storage roll and passes an applicator which on the other side of the aluminium foil or aluminium foil laminate applies a continuous layer of PEN, PTN or an LCP, by means of an extrusion coating device. The thickness of the aluminum foil is within the range of 5 – 50 µm, preferably within the range of 8 – 20 µm. The amount of applied polymer may vary, but the thickness thereof is preferably such that a well integrated and substantially 20 intact layer is formed after drying. A suitable thickness range of PEN, PTN or an LCP is 1 – 100 µm, preferably 8 – 50 µm.

25 Subsequently patch pouches are manufactured by dividing the laminate into two sheets forming an upper and a lower part of the patch pouch. Subsequently and by means of a vacuum device a nicotine-containing patch is placed on one of the sheets whereupon the other sheet is placed on the patch. Finally the sheets are heat sealed together along their edges to form a pouch.

In Example 1 the nicotine impermeable materials are used to make a package which totally encloses a nicotine-containing product. The present materials are also useful for partially enclosing and/or for sealing a package for a nicotine-containing product. 30 PEN, PTN and LCP, may also be used for all other applications where presently Barex® is used. One such application is the sealing of polymer tubes, containing polymer plugs with nicotine, for the nicotine inhaling device presently marketed by Pharmacia & Up-

john and in essence being disclosed in US 5,501,236. Also said polymer tubes may be made of the materials according to the present invention. Such tubes may e.g. be made by injection molding. The materials may also be used in blisters for nicotine chewing gums or tablets and for sealing glass flasks containing nicotine nasal spray.

5 The materials are also suitable for packages wherein dosage forms such as tablets, lozenges or similar are cast directly into the package. Thereby the package is to the extent necessary formed as mould(s) into which is cast the substance to be formed into tablets, lozenges or similar, said material achieving its final shape and form upon solidification in the package. In each such package may e g be cast one or more tablets, lozenges etc. After casting the package may be folded or likewise to provide for a nicotine-impermeable package for the cast tablets, lozenges etc. If necessary the package material 10 may be provided with some added material or thin sheet accounting for that the substance which is cast will not stick to the package material.

CLAIMS

1. A material for packaging a nicotine-containing product, characterized in that it comprises a polymer based on dimethyl-2,6-naphthalene dicarboxynate and/or 2,6-naphthalene dicarboxylic acid monomers.
2. A material for packaging a nicotine-containing product, characterized in that the material comprises a liquid crystal polymer, LCP.
- 10 3. A material according to claim 1, characterized in that the polymer is polyethylene naphtalate, PEN.
4. A material according to claim 1, characterized in that the polymer is polytrimethylene naphtalate, PTN.
- 15 5. A material according to claim 2, characterized in that the LCP comprises hydroxy benzoic acid and hydroxy naphtenic acid.
6. A material according to any one of the preceding claims, characterized in that it further comprises other polymer(s), preferably one or more of polyacrylonitrile (PAN), polyamide (PA), polyvinylidene chloride (PVDC), fluoropolymers, ethylene vinyl alcohol copolymer (EVOH), polyvinyl alcohol (PVA), ionomers, polyethylene (PE), and polypropylene (PP) and polyethylene terephthalate (PET).
- 25 7. A material according to anyone of the preceding claims, characterized in that it is laminated with one or more metal and/or polymer foil(s).
8. A material according to claim 7, characterized in that it is laminated with aluminum foil.

9. A material according to anyone of the preceding claims, characterized in that it is used for totally enclosing, partially enclosing and/or for sealing a package for a nicotine containing product.

5 10. A material according to anyone of the preceding claims, characterized in that it is used for a package that is provided with moulds or equivalent into which is cast a substance that upon solidification in the package receives its final form and shape.

10 11. A material according to claim 10, characterized in that it is used for a package in which are directly cast tablets or lozenges.

15 12. A material according to anyone of the preceding claims, characterized in that it is used for packaging a patch for transdermally administering nicotine, a nicotine containing chewing gum, a nicotine containing tablet, a spray for nasal administration of nicotine, or a device for inhaling nicotine.

13. Use of a material according to anyone of the preceding claims for the manufacturing of a package for keeping nicotine-containing products.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 00/00017

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: B32B 27/06, B65D 75/26, C08G 63/189, C08G 63/60
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: B32B, C08G, B65D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 9109731 A1 (ALZA CORPORATION), 11 July 1991 (11.07.91) --	1-13
A	US 5225199 A1 (OSAFUMI HIDAKA ET AL), 6 July 1993 (06.07.93) --	1,3-4,6-13
A	EP 0656389 A1 (NKK CORPORATION), 7 June 1995 (07.06.95) --	1,3-4,6-13
A	US 5326848 A (TSUGUNORI KASHIMURA ET AL), 5 July 1994 (05.07.94) -----	2,5-13

Further documents are listed in the continuation of Box C.

See patent family annex.

- * Special categories of cited documents
- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed
- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 May 2000	18-05-2000
Name and mailing address of the ISA: Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. + 46 8 666 02 86	Authorized officer Helena Danielsson/Els Telephone No. + 46 8 782 25 00

INTERNATIONAL SEARCH REPORTInternational application No.
PCT/SE00/00017**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).:

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see next page

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
 No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE00/00017

- I. Claim 1, 3-4 and parts of 6-13 relates to a material for packaging a nicotine-containing product, which material comprises a polymer based on dimethyl-2,6-naphthalene dicarboxynate and/or 2,6-naphthalene dicarboxylic acid monomers.
- II. Claim 2, 4 and parts of 6-13 relates to a material for packaging a nicotine-containing product, which material comprises a liquid crystal polymer, LCP.

The special technical feature of invention I is a polymer based on dimethyl-2,6-naphthalene dicarboxynate and/or 2,6-naphthalene dicarboxylic acid monomers.

The special technical feature of invention II is a polymer based on a liquid crystal polymer.

The special technical feature of invention II is not the same as or corresponding to the special technical feature of invention I.

INTERNATIONAL SEARCH REPORT

Information on patent family members

02/12/99

International application No.

PCT/SE 00/00017

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO 9109731 A1	11/07/91	AT 166029 T AU 639073 B AU 7167491 A CA 2032446 A DE 69032313 D,T EP 0506860 A,B SE 0506860 T3 ES 2114885 T FI 922811 A NO 300880 B NZ 236487 A PT 96221 A,B US 5077104 A US 5256956 A US 5268209 A		15/05/98 15/07/93 24/07/91 22/06/91 03/09/98 07/10/92 16/06/98 17/06/92 11/08/97 23/12/92 30/09/91 31/12/91 26/10/93 07/12/93
US 5225199 A1	06/07/93	AT 131384 T AU 637496 B AU 7658291 A CA 2062828 A,C DE 69115445 D,T DK 484543 T EP 0484543 A,B SE 0484543 T3 ES 2081477 T JP 2505674 B KR 9505865 B WO 9116044 A		15/12/95 27/05/93 11/11/91 25/10/91 20/06/96 22/01/96 13/05/92 01/03/96 12/06/96 02/06/95 31/10/91
EP 0656389 A1	07/06/95	US 5858490 A WO 9429374 A		12/01/99 22/12/94
US 5326848 A	05/07/94	JP 5186577 A DE 69129050 D,T EP 0466085 A,B JP 5001139 A JP 5001140 A JP 5005028 A		27/07/93 29/10/98 15/01/92 08/01/93 08/01/93 14/01/93